

SEP 18 2006

PREMARKET NOTIFICATION [510(K)] SUMMARY

This summary information is been submitted in accordance to the requirements of The Safe Medical Devices Act of 1990

Distributor : New World Medical, Inc.
10763 Edison Court
Rancho Cucamonga, CA 91730

Manufacturer : New World Medical, Inc.
10763 Edison Court
Rancho Cucamonga, Ca 91730

Telephone/Fax : 909/466-4304; Fax 909/466-4305

Company Contact Person : A. Mateen Ahmed, PhD/President

Trade Name : Ahmed Glaucoma Valve Model M4

Common Name : Glaucoma Implant

Classification : Class : II 886.3920
Panel : Ophthalmic (OP)
Product Code : KYF

Date Summary Prepared : June 5th, 2006

Substantial Equivalence :

The Ahmed Glaucoma Valve Model M4 is substantially equivalent to the Ahmed Glaucoma Valve Model S2 and S3 currently manufactured by New World Medical, Inc.

Intended Use :

The Ahmed Glaucoma Valve Model M4 is intended for use in patients with intractable glaucoma to reduce intraocular pressure where medical and conventional surgical treatments have failed.

General Description :

The Ahmed™ Glaucoma Valve (AGV) S3 is a valved aqueous drainage implant designed to regulate intraocular pressure in eyes suffering from intractable glaucoma. The Ahmed™ device is comprised of a silicone drainage tube that is connected to a valve membrane. The valve membrane is sandwiched between a top plate made of polypropylene and a complementary bottom plate made of polypropylene. The bottom plate is extended to provide for aqueous distribution and drainage. The valve body conforms to the shape of the globe at its equator and protects the valve from blockage by fibrous tissue growth.

The Ahmed Valve Model M4 valve system is exactly the same as the Models S2 and S3. The M4 valve system is enclosed within a porous material (MEDPOR®) made of polyethylene (MEDPOR® is well established as a safe material and has been approved by the FDA for ocular use).

An animal study comparing the AGV™-S3 and AGV™-M4 was conducted at Duke University. The study lasted for over six months and was successful in demonstrating the biocompatibility of the M4. In addition, it showed that the use of porous polyethylene in the M4 resulted in decreased collagen synthesis and increased vascularization in the tissue surrounding the implant when compared to the S3. Furthermore, resistance to outflow from the M4 to the surrounding tissue was significantly reduced when compared to the S3.(Dozier, 2006)



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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New World Medical, Inc.
c/o A. Mateen Ahmed, Ph.D.
President
10763 Edison Court
Rancho Cucamonga, CA 91730

Re: k060644

Trade/Device Name: Ahmed Glaucoma Valve Model M4
Regulation Number: 21 CFR 886.3920
Regulation Name: Aqueous Shunt
Regulatory Class: Class II
Product Code: KYF
Dated: August 25, 2006
Received: August 28, 2006

Dear Dr. Ahmed:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – A. Mateen Ahmed, Ph.D.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in dark ink, appearing to read "MB Eydelman, M.D.", with a stylized flourish at the end.

Malvina B. Eydelman, M.D.

Director

Division of Ophthalmic and Ear, Nose
and Throat Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Applicant : New World Medical, Inc.

510(k) Number (if Known): K060644

Device Name : Ahmed Glaucoma Valve Implant Model M4

Indications for Use:

The Ahmed™ Glaucoma Valve is indicated for the management of refractory glaucomas, where previous surgical treatment has failed, or by experience is known not to provide satisfactory results. Such refractory glaucomas can include neovascular glaucoma, primary open angle glaucoma unresponsive to medication, congenital or infantile glaucoma, and refractory glaucomas resulting from aphakia or uveitis.

Prescription Use ✓
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF
NEEDED)

J. J. Current of CDRH Office of Device Evaluation (ODE)
(Division Sign-Off)
Division of Ophthalmic Ear, (Per 21 CFR 801.109)
Nose and Throat Devices (Optional Format 1-2-96)

510(k) Number K060644